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To

Legislators on the Connecticut
Public Health, Human Services, and Insurance & Real Estate Committees

Regarding

Cost and Quality Issues in Health Care and
Specific Proposals to Address Prescription Drug Prescribing and Marketing

February 26, 2009

I want to thank the Committee members for the opportunity to submit this testimony today on behalf of Community Catalyst, a national non-profit advocacy organization dedicated to quality affordable health care for all. Community Catalyst works on a wide variety of health reform initiatives in over 45 states, and is also home to The Prescription Project, created by the Pew Charitable Trusts in 2006.

I have been asked to address the broad challenges we face today in protecting and improving quality in the health care system while reducing unnecessary costs that undermine both access and quality of care. I will also explore in more detail proposals that address the cost and quality of prescription drugs and medical devices, a sector that is an important driver of health care cost increases. These proposals will reduce the influence of pharmaceutical and device manufacturers on the prescribing process, while unbiased education and outreach to prescribers to better inform their clinical decision making.

In his address to Congress this week, President Obama committed his administration to aggressive action on the escalating cost of health through long overdue health reform. The administration also recognizes that these costs are a barrier to our economic recovery. States across the country are facing a crushing crisis as well, as state revenues fall, unemployment rises and people increasingly need help from our public coverage programs. According to the most recent State of the States Report from Robert Wood Johnson, at least 41 states and the District of Columbia are reporting mid-year budget gaps, amounting to an estimated $43 billion

shortfall. [1] The health care funds included in the stimulus package, as well as the reauthorization of S-CHIP are very important first steps in addressing these health care needs and state budget gaps, but we clearly have much more to accomplish at the federal and state levels.

Health Care Spending in the U.S.

Health care costs are growing so fast they are predicted to account for one-quarter of the nation's spending by 2025. While burdening consumers, employers, and state and federal governments, the $2.1 trillion we spend annually on health care[2] is delivering poor results. Increasingly, the health care debate in the United States is focused on how to slow down costs and get more for our dollar. However, we must adopt approaches to this crisis that protect consumers and access while improving quality and affordability of care.

Health care costs are soaring

The United States spends twice per capita compared to other industrialized nations on health care.[3] Costs continue to soar, outpacing the growth of our economy as a whole. If the current rate of growth were to continue, health care spending would increase from 16 percent of gross domestic product (GDP) in 2007, to 25 percent by 2025 and then to 49 percent by 2082.[4]

This trend is troubling on two levels. First, when compared to other countries, the extra money we devote to our health care system is not improving the health of the nation. Second, growing health care costs are being shifted to insured consumers in the form of lower wages, higher premiums and cost-sharing, all of which are contributing to the growing ranks of the uninsured.

Hospital care accounts for 30% of health care costs, the largest component. Physician services are the next highest, with 15% of the share of costs. Prescription drugs account for 10% of total costs but are one of the fasted growing components of health care spending. Other professional services account for another 10%, followed by program administration at 7%.[5]

According to an analysis by the Henry J. Kaiser Foundation, the major factors driving the growth in these expenditures are:

- Increased intensity of services: Driven by increased life spans and the prevalence of chronic illnesses.

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[1] Academy Health, State of the States. "Charting a CourseL Preparing for the Future, Learning from the Past." January, 2009.
[2] Total U.S. health expenditures reached $2.1 trillion in 2006 according to CMS (report available here.)
[3] The Commonwealth Fund Commission on a High Performance Health System, Why Not the Best? Results from the National Scorecard on U.S. Health System Performance, 2008, 2008), .
[4] Congressional Budget Office, The Long-Term Outlook for Health Care Spending, 2007.
[5] The Henry J.Kaiser Family Foundation. "U.S. Health Care Costs" http://kaiseredu.org/topics accessed 2-24-09

- Prescription drugs and technology: After six years of slowing growth, prescription drug spending accelerated in 2006, due in large part to Medicare Part D. Less is known about the impact of other medical technologies.
- Aging of the population: Health care costs increase with age, contributing to rising costs as more of us retire, require more services and depend more on public sector programs.
- Administrative costs: Marketing, billing and other administrative costs average 7% of the health care dollar, much higher than in public programs such as Medicare (less than 2%) and Medicaid.

More health care spending does not necessarily lead to better health care

Despite its higher expenditures, the United States provides neither more coverage nor better care than other industrialized nations. Unlike other countries that cover all of its citizens, the current American system excludes millions of families from health insurance coverage, and it also provides a lower quality of care compared to other developed nations. A study by the Commonwealth Fund found that health care systems in comparable countries consistently outperformed the United States on measures of quality, access, equity and outcomes.[6] For example, the United States ranked last out of 19 countries on the number of deaths that might have been prevented with timely and effective care.

In addition, both health care costs and quality vary dramatically throughout the United States. For example, spending adjusted for sex, age and race for traditional Medicare in 1996 was $8,414 per enrollee living in or near Miami, Fla. compared with $3,341 per enrollee living in or near Minneapolis, Minn.[7] Research shows that while Medicare enrollees in the high-spending regions received *more* health care than their counterparts in lower-spending regions, they did not receive better quality care, experience higher satisfaction with their care, or enjoy better health outcomes[8].

The current system wastes money on ineffective care and high administrative costs

This seemingly paradoxical relationship between cost and quality can be partially explained by an important point: our health care system relies heavily on expensive, inefficient and unsafe care, and this costly care often replaces the use of more effective procedures. Though they do not have higher rates of illness, high-cost regions deliver care in more expensive settings. They tend to provide care for chronic diseases in inpatient settings, and overuse expensive specialist services. These regions also overuse diagnostic tests and minor medical procedures that are not proven to enhance the quality of care.[9] Despite

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[6] The Commonwealth Fund Commission on a High Performance Health System, December, 2007.
[7] E. S. Fisher, et al, "The Implications of Regional Variations in Medicare Spending. Part 1: the content, quality and accessibility of care." Annals of Internal Medicine 138.4 (2003).
[8] Fisher, et al, 273, E. S. Fisher, et al, "The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care," Annals of Internal Medicine 138.4 (2003).
[9] Fisher, et al, 288

their increased costs, these areas score worse on simple measures of health care quality, such as the administration of beta-blockers after heart attacks, mammograms for older women, influenza vaccines, and eye exams for diabetics.[10]

The availability of more expensive, new drugs and technological services fuels spending not only because industry must recoup development costs, but also because the availability of these technologies, combined with aggressive marketing campaigns to prescribers and consumers, generates demand for more intense, costly services even if they are not necessarily the best, most cost-effective treatment choices.[11]

Furthermore, the United States devotes a higher fraction of its total health care spending to administrative costs than any other industrialized nation. According to one study, the combination of employers' costs to manage health care benefits, hospital, nursing home and home care agency administration, and the administrative costs of practitioners accounted for 31 percent of all U.S. health expenditures in 1999. The same study found that administrative costs accounted for only 16.7 percent of Canada's health expenditures.[12]

These higher administrative costs are a result of many unique characteristics of the American health care system. For example, insurance companies devote significant resources to assessing applicants' medical risk. This administrative complexity is then passed on to providers, who have to hire multiple billing specialists to make sense of the wide variety of care packages, prior-approval rules and drug formularies associated with the different insurance companies. Not all administrative overhead is wasteful; some administrative services add value to the care delivered, like provider quality monitoring and mailings to beneficiaries about important preventive services. Most administrative overhead, however, add nothing to the quality of care in the United States, and it consumes a significant portion of our health care budget.

Increased costs are shifted onto vulnerable individuals

As overall health care expenditures rise, the burden trickles down to individual consumers in the form of increased premiums and cost-sharing. Nineteen percent of the population paid more than 10 percent of their incomes towards health care costs in 2003, up from 16 percent in 1996. Rising health care costs cut away disproportionately at the incomes of individuals below the Federal Poverty Level (FPL): One-third of impoverished families spent more than 10 percent of their incomes on health care in 2003, up

[10] K. Baicker and A. Chandra, "Medicare Spending, the Physician Workforce, and Beneficiaries' Quality of Care," Health Affairs web exclusive (2004).
[11] Henry J. Kaiser Family Foundation, January 2009.
[12] S. Woolhandler, T. Campbell, and D. Himmelstein, "Costs of Health Care Administration in the United States and Canada," The New England Journal of Medicine 349.8 (2003).

from about one-quarter in 1996.[13] High costs are the number one reason cited by the uninsured for not having insurance. Working families are also paying for rising health care costs through declining wages. Researchers find that as employers face higher premiums for their employees' health care, they pass these costs directly to their employees by reducing the size of pay increases.[14]

Consumer-Friendly Solutions to the Health Care Cost and Quality Crisis

Although governments, employers and individuals are all burdened by rising health care costs, each stakeholder group is primarily concerned with reducing its own share of the costs. We must resist policies that shift costs from the most influential interest groups – insurers, providers and employers – onto individuals, rather than to tackle overall health care costs. ***Therefore, to best protect consumers and the public health, we recommend the adoption of policies that aim to slow the growth in aggregate health care costs, while improving the efficiency and effectiveness of medical care, without increasing the burden of out-of-pocket expenditures for consumers.***

Community Catalyst has identified eight consumer-friendly approaches to cost containment that also improve quality: (1) coordination of each patient's care (2) improving administrative efficiency (3) promoting primary care (4) investing in public health programs (5) creating incentives for better care (6) increasing oversight and regulation of cost growth (7) increasing consumer's purchasing power through purchasing pools and (8) establishing the effectiveness of new medical technologies and promoting the use of the best quality, most appropriate treatments.

In the remainder of my remarks, I will focus the remainder on the last of these strategies, specifically addressing three prescription drug proposals which have been introduced in Connecticut. Together these proposals are an integrated strategy to expand the use of evidence-based prescribing and combat industry marketing practices that inappropriately influence prescribing patterns and interfere with an unbiased, scientific and patient-centered approach to diagnosis and appropriate treatment. They are:

(1) Providing unbiased, evidence-based outreach and education to physicians, pharmacists and other health care professionals authorized to prescribe and dispense prescription drugs through a program of "academic detailing". (Bill No. 1050)

(2) Banning gifts and other inducements given to prescribers by prescription drug manufacturers (Bill No. 1049).

[13] The Henry J. Kaiser Family Foundation
[14] The Henry J. Kaiser Family Foundation

(3) Banning the sale of prescriber data for marketing purposes, which interferes with the provider patient relationship by arming the industry with data used to shape the sales pitches by pharmaceutical representatives. (Bill No. 1046)

The Prescription Project is working with policymakers, medical organizations and consumer organizations in twenty states and on the federal level to advance these approaches, and I have included more detailed fact sheets on these issues with my testimony.

Prescription Drug Costs

Nationally, spending on prescription drugs was $200.7 billion in 2005, five times higher than the $40.3 billion spent in 1990.[15] A significant portion of this increase can be attributed to pharmaceutical companies' success in achieving prescribing switches from effective, older, cheaper and often safer medications to newer, more expensive treatments. For instance, from 2000-2001, of the drugs responsible for the nearly 19% rise in spending on pharmaceuticals, the four top sellers were among the top ten most heavily marketed drugs. Furthermore, about one-quarter of the total increase in retail spending that year on prescription drugs was due to switches from cheaper to more expensive drugs.[16]

These increases in pharmaceutical costs are driven in part by a massive investment by the pharmaceutical industry in marketing, particularly to physicians, who are the key decision makers in prescribing. Overall, the pharmaceutical industry spent $29 billion on promoting and marketing prescription drugs in 2005, with $7.2 billion spent on marketing directly to physicians[17], for an average of about $8,800 per physician, per year. The industry employs a sales force of over 90,000 representatives or "detailers"[18] – about one for every nine physicians – to promote company products and distribute gifts. Studies suggest that promotional materials are often misleading or inaccurate[19] and that physicians are not always able to identify bias. Research also shows that exposure to promotion causes significant changes in prescribing.[20]

Cost increases driven by this massive marketing effort are passed along to patients, public programs and other payers. While the industry argues that the high costs of pharmaceuticals is due to needed research

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[15] Kaiser Family Foundation. Prescription Drug Trends. 2007.
[16] Dana, Jason and George Loewenstein. "A Social Science Perspective on Gifts to Physicians From Industry." JAMA. 2003;290:252.
[17] Donohue, J., Cevasco, M., Rosenthal, M. A Decade of Direct-to-Consumer Advertising of Prescription Drugs. *New England Journal of Medicine.* 2007; 357: 673-681.
[18] Medical Marketing and Media, *Sales Force Report: Sales Makeover,* November 2007. Available at: http://www.imshealth.com/vgn/images/portal/cit_40000873/44638321119 53_eprint.pdf Accessed September 12, 2007.
[19] Drug representatives' Claims to Physicians Not Always Accurate. American Journal of Health System Pharmacy 1995; 52(14):1504-1506.
[20] Peay & Peay (www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2905075&dopt=Citation), Orlowski & Wateska (http://www.chestjournal.org/cgi/content/abstract/102/1/270), Gonul et al. "Promotion of Prescription Drugs and Its Impact on Physicians' Choice Behavior." *Journal of Marketing*, 2001, Vol. 65 (July), pp. 79-90.

and development costs, the reality is that marketing accounts for 30% of the total cost of prescription drugs, [21] about double the amount spent by pharmaceutical companies on research and development.[22]

Inappropriate prescribing not only inflates costs, but undermines quality of care. Examples include:

- **Avoidable deaths due to Vioxx®.** Studies showed that Vioxx, the pain killer manufactured by Merck, was no better for the vast majority of patients than older, less expensive drugs. However, Merck spent $500 million annually to market Vioxx and sales were $1.3 Billion in the first nine months of 2004 before it was taken off the market. Overall 20 million people took Vioxx and up to 55,000 deaths,[23] about 40% of 139,000 cardiac incidents, may have occurred due to cardiovascular problems and heart attacks suffered by patients taking the anti-inflammatory drug before it was withdrawn from the market. In contrast, an evidence-based decision-making process in the state of Washington led to a 2002 judgment not to add Vioxx to its preferred drug list – years before the safety concerns became well-known.[24]
- **Illegal promotion of Neurontin®.** The pharmaceutical company Warner Lambert promoted the epilepsy medication Neurontin for unapproved uses. The Massachusetts Attorney General joined with the Department of Veterans Affairs and the federal Department of Justice to successfully sue the company for a total of $430 million in damages for losses the Medicaid programs suffered as a result of Warner-Lambert's fraudulent drug promotion and marketing misconduct.
- **Inappropriate use of Epogen® and Procrit®.** Recent studies have shown that physicians, dialysis clinics and the pharmaceutical industry profited from the over prescribing of the anemia drugs, Epogen and Procrit, compromising patient safety and driving up costs.
- **Over-reliance on new drugs.** Without clear health benefits, reliance on newer drugs is also riskier than using more established products. One fifth of all prescription drugs introduced to the market are recalled or receive blackbox warnings within twenty-five years[25].

Physician Education and Outreach ("Academic Detailing")

Academic Detailing programs address these issues by promoting unbiased, evidence-based prescribing through an outreach and education program designed to provide information on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists and other health care professionals

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[21] Angell M. The Truth about Drug Companies: How They Deceive Us and What to Do About It. Random House, August 24, 2004

[22] Brekke, KR and Kuhn, M. "Direct to consumer advertising in pharmaceutical markets." J Health Econ. 2006 Jan;25(1):102-30. Epub 2005 Nov 8

[23] Testimony of David J. Graham, MD, MPH. U.S. Senate Committee on Finance November 18, 2004. (http://www.senate.gov/~finance/hearings/testimony/2004test/111804dgtest.pdf)

[24] The Prescription Project. Washington: Practicing evidence-based medicine http://www.prescriptionproject.org/casestudies/public_policies_and_programs?id=0002

[25] Lasser KE, Allen PD, Woolhandler SJ, Himmelstein DU, Wolfe SM, Bor DH. Timing of new black box warnings and withdrawals for prescription medications. *Journal of the American Medical Association* May 1, 2002; 287: 2215 - 2220.

authorized to prescribe and dispense prescription drugs. Such programs provide a substitute for the biased information provided by pharmaceutical industry detailers (sales representatives) who engage in one-on-one encounters with physicians and increasingly, nurse practitioners and physician's assistants. This is the most prevalent method used by pharmaceutical companies to market their products to prescribers.

Many doctors report that they are constrained by their schedules and patient volume and therefore use drug sales representatives as their primary source of available information on prescription medications. Yet detailers generally have only a bachelor's degree and no background in science—they come armed with free samples, lunches, golfing trips, methods to flatter and bond with the targeted physician, and a short, biased, highly structured sales pitch. Studies show that drug sales representatives' statements on their products are often misleading or inaccurate and that physicians are not always able to identify bias[26].

In February 2007, researchers at the Prescription Project published an article in the Journal of General Internal Medicine on physician interactions with drug representatives, based on a series of focus groups. Participating physicians emphasized the educational aspects of relationships with detailers. One said: "A lot of the things I know about the new drugs, I learned from the pharmaceutical representatives." Most denied being influenced by the industry "spin" [27]. The results suggest that voluntary codes to limit industry gifting and influence are not working and that academic detailing, which provides the means to reach out to physicians in these group practices, in their offices, could be an important way to provide needed clinical consults to prescribers.

How does academic detailing work? Jerry Avorn, Professor of Medicine at Harvard Medical School and chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, developed the concept and has been studying drug treatment and outcomes for over 25 years. In a June 1983 NEJM publication with Steve Soumerai, Avorn reported results of a well-designed study comparing the prescribing of doctors who were offered education visits with those who were not in four states. The study showed that the visits substantially and significantly reduced the number of prescriptions for three often over-used drugs. [28] Avorn and Soumerai have defined the most important techniques of "academic detailing" as follows:

(1) conducting interviews to investigate baseline knowledge and motivations for current prescribing patterns;

(2) focusing presentations on specific categories of physicians as well as on their opinion leaders,

[26] Ziegler MG, Lew P, Singer BC. The accuracy of drug information from pharmaceutical sales representatives. *JAMA*. 1995;273:1296-1298.Comments in JAMA. 1995;274:1267-1268.

[27] Chimonas et al. Physicians and Drug Representatives: Exploring the Dynamics of the Relationship. Journal of General Internal Medicine. February: 22 (2): 184-190. 2007.

[28] Volume 308:1457-1463; June 16, 1983; Improving drug-therapy decisions through educational outreach. A randomized controlled trial of academically based "detailing" J Avorn, and SB Soumerai

(3) defining clear educational and behavioral objectives,

(4) establishing credibility through a respected organizational identity, referencing authoritative and unbiased sources of information, and presenting both sides of controversial issues,

(5) stimulating active physician participation in educational interactions,

(6) using concise graphic educational materials,

(7) highlighting and repeating the essential messages, and

(8) providing positive reinforcement of improved practices in follow-up visits. Used by the nonprofit sector, the above techniques have been shown to reduce inappropriate prescribing as well as unnecessary health care expenditures[29].

Academic detailers have no other agenda than providing the best, most up-to-date information to doctors. While in some cases a newer, more expensive drug is the best treatment option for a patient, there are often older, cheaper generic medicines available that have proven track records in effectiveness and safety. Academic detailers base their recommendations on pharmaceutical efficacy, adverse effects of drugs and evidence-based treatment options.

Examples of academic detailing programs include:

- Pennsylvania's academic detailing initiative program for PACE, the Department of Aging's prescription drug program for seniors. A recent evaluation shows that, in a little over a year's time, the program has positively impacted prescribing practices and has been well-received by the physician community. Dr. Avorn's Independent Drug Information Service at Brigham and Women's Hospital runs the PACE program. (see http://www.rxfacts.org) The state is planning to expand the program within PACE and to the state employee plan as well.
- Kaiser Permanente and Health Partners, both staff model HMOs which limit drug industry interaction with their participating physicians, also take an evidence-based approach to recommendations and physician education on prescribing. An indication of the impact is that Kaiser has a generic drug prescribing rate of 70%, while the national average is 56%. [30]
- Vermont established a program in 2004 in cooperation with the University of Vermont and the Vermont Area Health Education Center, and in 2006, the Vermont Legislature voted to increase funding in order to expand the program. (see http://www.med.uvm.edu/ahec)

[29] JAMA. 1990 Jan 26;263(4):549-56. Principles of educational outreach ('academic detailing') to improve clinical decision making. Soumerai SB, Avorn J

[30] *Testimony of Bruce C. Perry, MD. on behalf of Kaiser Permanente Medical Care Program,* in the Committee on Energy and Commerce, Subcommittee on Health, U.S. House of Representatives. 2005. Washington, D.C.

- In 2006 the Maine legislature passed a bill to establish a program and allocated start-up funds. They are now collaborating with New Hampshire, which passed a bill in 2008, and with Vermont, on implementation. (see the white paper at www.policychoices.org.)
- Massachusetts, New York and the District of Columbia passed bills in 2008 and have contracted with Dr. Avorn's group to manage part or all other their programs.
- Academic detailing programs have been conducted on a large scale in countries such as Australia and Canada. Governments have continue to fund such programs because they are effective.

I am also submitting a detailed review of the literature, particularly focused on the cost-effectiveness of academic detailing programs in the U.S. and other countries. The literature shows that the potential for academic detailing to generate savings through the prescribing of therapeutically equivalent but more cost-effective drugs is immense.

- By one estimate, increased use of generics alone would produce national savings of about $8.8 billion dollars per year. [31]
- Looking only at a single condition, hypertension (high blood pressure), the evidence shows that for most patients the first choice drug should be an inexpensive thiazide diuretic instead of one of several new, expensive and heavily marketed drugs. The potential US saving from appropriate use of thiazides is estimated at $433 million a year. [32]And published evidence shows that academic detailing drives this shift in a cost-effective way.[33]
- There are even greater potential cost savings through changes in prescribing that prevent disease.

Gifts bans and disclosure

A gift ban and disclosure of other payments to prescribers would provide important controls and transparency to address aggressive marketing by pharmaceutical and device manufactures. Such marketing campaigns include gifts ranging from the seemingly trivial[34] (e.g. pens, coffee mugs, prescription pads, "modest" meals) to substantial educational grants and lavish trips and entertainment. Surveys indicate that the "gift relationship" with the pharmaceutical industry begins early in physicians'

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[31] Haas J et al. Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000. Ann Intern Med 2005; 142: 891-897

[32] Fretheim A, Aaserud M, Oxman AD. The potential savings of using thiazides as the first choice antihypertensive drug: cost-minimisation analysis. BMC Health Serv Res. 2003 Sep 8;3(1):18.

[33] Simon SR, Rodriguez HP, Majumdar, SR, et al. Economic analysis of a randomized trial of academic detailing interventions to improve use of antihypertensive medications. *Journal of Clinical Hypertension (Greenwich, Conn.),* 2007; *9*(1): 15-20

[34] The PhRMA code defines "token" as less than $100.

careers. One study found that residents received an average of 75 "giveaway" items per year.[35] Food is one of the most common industry gifts. In some offices, lunch is provided every day by a different company.[36] Despite the common view that "token" gifts are not influential, social scientists have demonstrated that even small gifts create a sense of obligation and reciprocity. Although many physicians will insist otherwise, research demonstrates conclusively that influence occurs regardless of the size of the gifts and whether the motives of the giver are transparent.[37]

A recent national survey of over 3000 physicians, published in the New England Journal of Medicine and funded by the Institute on Medicine as a Profession, found that 94% of physicians reported some type of relationship with the pharmaceutical industry, despite voluntary guidelines limiting such relationships published in recent years by the Pharmaceutical Research and Manufacturers of America, the American Medical Association and the American College of Physicians. Physicians in group practice were six times more likely to receive samples, three times as likely to receive gifts, and four times as likely to receive payments for professional services as physicians in hospitals, clinics and staff model health maintenance organizations. [38]

Interactions between drug companies and physicians undermine public trust in the profession. Surveys indicate that patients view industry gifts as less acceptable than do physicians. Patients are also more likely than physicians to believe that gifts influence prescribing and increase healthcare costs.[39] News accounts have spotlighted a number of prominent legal cases in which physician-industry exchanges were so excessive as to implicate the anti-kickback statute.

Research suggests that a ban on most industry gifts to prescribers would be the most effective means of eliminate their negative effects. The gifts ban and complementary disclosure law in Minnesota, passed in 1993, also illustrates the value of disclosure as a complement to a ban. The Minnesota statute bans gifts with a value of over $50. Payments of over $100 that are excluded from the ban, including research, must be disclosed by the industry and are reported to the public, by individual prescriber name, type and amount of payment. Despite uneven reporting by the industry, the Minnesota data linked to specific physicians has revealed:

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[35] Komesaroff, P.; Kerridge, I. Ethical Issues Concerning the Relationships between Medical Practitioners and the Pharmaceutical Industry. *MJA* 2002: 176(3): 118-121.
[36] http://www.nytimes.com/2006/07/28/business/28lunch.html?ex=1156564800&en=80c2281724faab3c&ei=5070
[37] Wazana, A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA*. 2000;283(3):373-380.
[38] Campbell et al. A National Survey of Physician-Industry Relationships. The New England Journal of Medicine,. 356;17. April 26, 2007.
[39] Gibbons et al. " A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts." JGIM 1998; 13: 151-154.

- Payments of ten of thousands of dollars to individuals on high stakes committees such as those that develop clinical guidelines or determine which drugs are used in Medicaid programs;[40]
- As payments from drug makers to psychiatrists in that state increased, so did the writing of prescriptions for drugs made by those companies. Those psychiatrists who received at least $5,000 from drug makers appear to have written more prescriptions than those who received less or no money;[41] and
- A number of doctors who had and continue to be paid by drug companies to conduct clinical trials or promote certain medicines had been sanctioned by the State Board of Medicine, for disregarding the welfare of patients.[42]

Massachusetts passed a gifts ban and disclosure law similar to Minnesota's last year and is in the process of writing regulations. Vermont, Maine, the District of Columbia and West Virginia have disclosure laws, but payments are not disclosed except in the aggregate to the public. Many states are currently considering bills, and Minnesota and Vermont are seeking to strengthen their statutes. In addition, the Physician's Payment Sunshine Act, (S. 301) has been introduced in the U.S. Senate by Senators Grassley, Kohl and Klobuchar, which would require drug, biologic, and medical device manufacturers to report certain gifts and payments made to physicians in a national and publicly accessible online database. [43]

Banning the sale of prescriber records for marketing purposes

Another component of a unified strategy to address inappropriate prescribing is a ban on the sale or use of prescriber records for marketing purposes. The pharmaceutical industry uses such data mining to influence physicians to prescribe their products, thereby interfering with the patient-physician relationship and driving inappropriate or more costly prescribing.

How does this work? When a patient fills a prescription at a major pharmacy, a record of that prescription (minus patient name) is sold to companies – so-called *health information organizations* – that pool information from multiple pharmacies. The bundled information is combined with individual physician identities purchased from the American Medical Association to create prescriber profiles (name, specialty, practice site, which and how many prescriptions written, etc.) that are sold to the drug companies.

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[40] Harris, G. Doctors' Ties to Drug Makers Are Put on Close View. *The New York Times*, March 21, 2007; Lohn, M. Minnesota Law Sheds Light on Drug Companies. Associated Press, August 22, 2007.
[41] Harris, G, Carey, B, Roberts, J. Psychiatrists, Children and the Drug Industry's Role. *The New York Times*, May 10, 2007.
[42] Haris, G, Roberts, J. After Sanctions, Doctors Get Drug Company Payments. *The New York Times,* June 6, 2007.
[43] See www.prescriptionproject.org for a fact sheets and more information.

Drug companies then give the information to their salespeople, who use it to tailor marketing strategies, messages, gifts and other inducements for individual physicians.[44] As a result, many patients are prescribed expensive medicines that are no better, and may be worse, than other available medicines or non-pharmacological therapies.[45] For example, Dendrite International touts its data mining product as follows: "[N]ow, pharmaceutical manufacturers who partner with Dendrite can gain a level of insight that allows them to predict and influence physician prescribing behavior like never before."[46]

Bill No. 1046 would address this issue in Connecticut. Data mining statutes are now in place in New Hampshire, Vermont and Maine, as described below. Like these statutes, the proposed legislation restricts only the sale and use of patient or prescriber data specifically for marketing or commercial purposes. It does not restrict the sale and use of such identifiable data for other purposes, including for insurance reimbursement, dispensing prescriptions, utilization review, public health research, law enforcement purposes, controlled substances monitoring, adverse effects reporting, or compliance with Medicaid or private insurance formularies and rules.

- *New Hampshire*: The Prescription Privacy Law (2006) prevents patient and prescriber identifying data from being sold or used for advertising, marketing, promotion or any activity intended to influence sales or market share of a pharmaceutical product The law was passed as a consumer protection and public health measure, and seeks to ensure privacy in prescribing.[47]
- *Vermont*: As part of a comprehensive package to control the costs of prescription drugs and regulate inappropriate marketing tactics, Vermont passed legislation in 2008 that provides strong privacy protections by limiting the use of personally identifiable prescription information for marketing purposes unless doctors and other health care providers explicitly agree to waive the protections. The law includes a physician *opt-in* provision at the time of licensure or renewal.[48]
- *Maine*: Maine also passed legislation requiring its Board of Licensure to include confidentiality

[44] National Physicians Alliance, Issue Brief: The Sale of Physician Prescribing Data Raises Health Care Costs – the National Physicians Alliance Calls for a Ban

[45] Schaefer, B. Restuccia, R. Mining Our Own Business. *Kennebec Journal*. April 13, 2007. Available at: http://kennebecjournal.mainetoday.com/view/columns/3795317.html Accessed August 15, 2007.

[46] Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction, IMS v. Ayotte, No. 06-CV-280-PB, at 13 (D.N.H. filed April 30, 2007). (Memorandum filed September 1, 2006).

[47] http://www.gencourt.state.nh.us/rsa/html/XXX/318/318-47-f.htm.

[48] Vermont Medical Society Statement on Governor Douglas' Signing of S.115. Vermont Medical Society Website. 2007. Available at: http://www.nlarx.com/policy/pdfs/VMSStatement_Gov_Signing_S115_RxBill.pdf. Accessed August 15, 2007.

protection of prescribing data as part of its licensure and license renewal process. [49] The Board must inform applicants that their prescription drug information is used for marketing purposes and how the prescribers may "opt out," a weaker alternative to the prescribing data protection systems in Vermont and New Hampshire.

The AMA's inadequate response

The response of the American Medical Association (AMA) to concerns about data-mining has been weak. The AMA plays a key role in enabling the data-mining industry by selling its physician database to data-mining companies. The AMA "Physician Masterfile" contains the name, identity, practice location, training site, licensure and disciplinary history for nearly every U.S. physician – even the two-thirds of doctors who are not AMA members. Sale of Masterfile data brought the AMA $44.5 million in 2005. Although the AMA initiated an option in 2006 to allow physicians to "opt out" of this program, the process is cumbersome and few physicians are aware of the option. [50]Moreover, even when a doctor "opts out," the AMA continues to sell that doctor's personally identifiable prescribing information. Pharmaceutical companies may still use the information to target their marketing efforts, as long as they pledge not to provide that individual prescriber's data directly to salespeople. Furthermore, the collection of prescribing data and identities through pharmacies is not affected by the AMA policies.

Industry Challenges

The data mining industry has challenged the New Hampshire, Maine, and Vermont statutes. The Federal District Court of New Hampshire overturned the law on constitutional free speech grounds. The State of New Hampshire appealed the decision, asserting that the state has a substantial interest in protecting the confidentiality of prescribe[illegible] from use for drug marketing purposes. On November 19, 2008, the Court of Appeals for the First Circuit overturned the ruling of the district court, and unanimously upheld the New Hampshire law. The Court found that the law regulates conduct, rather than protected speech, and that it is further justified by the state's substantial interest in promoting containment of prescription drugs costs.

"There is a second basis for our decision. Even if the Prescription Information Law amounts to a

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[49] Maine Public Law, Chapter 460. Available at: http://janus.state.me.us/legis/LawMakerWeb/externalsiteframe.asp?ID=280022219&LD=4&Type=1&SessionID=7. Accessed August 27, 2007.

[50] American Medical Association. Description of AMA Physician Masterfile Data Elements. 2004. Available at: https://profiles.ama-assn.org/amaprofiles/info/pdf/mfile_elements.pdf Accessed: August 25, 2007.

regulation of protected speech — a proposition with which we disagree — it passes constitutional muster. In combating this novel threat to the cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands."[51]

The challenge in Maine is covered by the First Circuit's ruling and it is therefore very likely that the Maine law will be upheld. The Vermont lawsuit is governed by the law of the Second Circuit Court of Appeals, which has not yet ruled on this issue. That lawsuit will continue, although it is likely to be affected by the forceful reasoning of the First Circuit panel in the New Hampshire case.

The Prescription Project would be glad to assist you in addressing any concerns arising out of these legal challenges. However, given the First Circuit decision, we are confident that the court has cleared the way for Connecticut and other states to act in this area to protect the public interest.

Conclusion

Rising health care costs are outpacing the growth of our economy, government revenues and workers' wages, and forcing our country into a serious debate about how best to contain health care costs. Although they already shoulder the burden of these increasing costs through stagnated wages, increased premiums and out-of-pocket expenditures, working families would be made worse off by many proposed cost containment policies that shift even more costs onto consumers. Community Catalyst advocates for a consumer-friendly cost containment agenda, including the prescription drug measures I have outlined today. These measures will make an important contribution to slowing aggregate health care costs, while improving the efficiency and its effectiveness of medical care.

Thank you very much.

Marcia Hams
Community Catalyst and
The Prescription Project

[51] IMS Health Inc. and Verispan, LLC v. Kelly A. Ayote, New Hampshire Attorney General, (1st Cir. 2008). Available at: http://www.ca1.uscourts.gov/pdf.opinions/07-1945P-01A.pdf